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### REMARKS

In accordance with the foregoing, pending claims 1, 3-14 are herein amended and claims 1-14 are presented for examination on the merits. Because the ~~remaining pending claims 2(i.e.,)~~ directly or indirectly depends from the amended claim 1s, ~~it they too stands indirectly~~ amended herein.

Applicants respectfully request entry and favorable consideration of said amended claims and the remarks presented herein. The following remarks are respectfully submitted.

I. Objection to the Drawings under 37 CFR §1.83(a)

The Examiner objected to the drawings under 37 CFR §1.83(a) and asserted that the drawings must show every feature of the invention specified in the claims; in particular, the Examiner states that "the subcutaneous electrodes" (recited in claim 1) and the "plurality of filters" (recited in claim 6) must be shown or the feature(s) canceled from the claims.

Applicants respectfully assert that the subcutaneous electrodes in fact already appear in the drawings (FIG. 4) and herewith presents at least one corresponding reference to the electrodes (denoted by reference numerals 51 and 54) from the application as filed (from page 12, ln. 8-14):

Continuing with FIG. 4, three or four (not shown) feedthrough/electrode assemblies 51 are welded into place on the flattened periphery of the pacemaker casing. In this embodiment, the complete periphery of the pacemaker may be manufactured to have a slightly flattened perspective with rounded edges to accommodate the placement of feedthrough/electrode assemblies such as those practiced in the present invention. These feedthrough/electrode assemblies 54 are welded to pacemaker casing (to preserve hermeticity) and are connected via wire 55 through feedthroughs 56 to electronic circuitry 52.

Moreover, Applicants respectfully assert that those of skill in art readily understand the nature and placement of such components and that when the

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claimed structures are present in a process or system claim, no drawing requirement exists. In support of this assertion, Applicants cite the Manual of Patent Examining Procedure (at §601(f)), entitled "Applications Filed Without Drawings." That is:

35 U.S.C. §111(a)(2)(B) and 35 U.S.C. §111(b)(1)(B) each provide, in part, that an 'application shall include . . . a drawing as prescribed by section 113 of this title' and 35 U.S.C. §111(a)(4) and 35 U.S.C. §111(b)(4) each provide, in part, that the 'filing date . . . shall be the date on which . . . any required drawing are received in the Patent and Trademark Office.' 35 U.S.C. §113 (first sentence) in turn provides that an "applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented." Applications filed without drawings are initially inspected to determine whether a drawing is referred to in the specification, and if not, whether a drawing is necessary for the understanding of the invention. It has been USPTO practice to treat an application that contains at least one process or method claim as an application for which a drawing is not necessary for an understanding of the invention under 35 U.S.C. 113 (first sentence). The same practice has been followed in composition applications. (emphasis added.)

Nevertheless, Applicants included two drawings (FIG. 6 and FIG. 7) in the application as originally filed depicting the subcutaneous electrodes array (graphically as "SEA" in conjunction with reference numeral "13").

With respect to the objection to the "plurality of filters" recited in claim 6, Applicants herewith respectfully assert that due to cancellation of the phrase, this ground of objection stands moot.

Therefore, Applicants respectfully assert that no proposed drawing correction is required. Accordingly, Applicants request the Examiner withdraw the present objection to the drawings.

## **II. Rejection under 36 USC §112, first paragraph**

Claim 14 stands rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

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at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that there is no teaching how the recited acronyms "PR," "AV" and "VA" are defined. *Applicants note that "PR" only expressly appears in claim 12, and have treated this rejection as standing against claim 12 and claim 14.*

Applicants respectfully disagree that one skilled in the art of cardiac pacing would even need any additional description regarding these well-known and often-used expressions for many, many decades (if not a century). Nevertheless, Applicants herewith amend (claim 12 and) claim 14 to spell out the words represented by these two-letter abbreviations (and set forth next to each said two-letter abbreviation). Accordingly, Applicants request the Examiner withdraw this ground of rejection.

**III. Rejection under 35 USC §112, second paragraph**

Claims 1-5 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner asserts that no antecedent basis exists for "the system." *Applicants respectfully assert that the term "system" is not present in un-amended claim 1 and therefore treat this rejection as standing against only claims 2-5.*

Applicants herewith amend claim 1 to introduce the term "system" therein thus rendering this ground of rejection moot. Accordingly, Applicants request the Examiner withdraw this ground of rejection.

**IV. Claim Rejections Under 35 U.S.C. §102(b)**

Claims 1-5 stand rejected under 35 USC § 102 as being anticipated by Bennett et al (US 5,331,966). Bennett et al. discloses the claimed circuit having a means for detecting atrial depolarization by the subcutaneous electrodes on a hermetically sealed case, a means for pacing having a pacing lead into the right

ventricle of a heart. Bennett further shows that the lead can be made from unipolar or bipolar leads.

Applicants respectfully assert that the present ground of rejection stands traversed if only a single element found in a rejected claim is not found in the single reference cited against said claim. Thus, while additional distinguishing features may be found to exist between the claimed invention and Bennett et al., Applicants only need point out a single distinguishing feature to traverse the rejection.

With respect to Bennett et al., Applicants respectfully assert that the presently claimed invention differs significantly in that the present invention provides means for detecting atrial depolarization signals *and means for pacing a ventricle synchronous with (at least one of) the detected atrial depolarization signals*. Bennett et al. describes and claims diverse ways of collecting EGM signals and storing them for diagnostic purposes, but does not provide pacing stimulus based on the EGM signals. In fact, the preamble of virtually every independent claim of Bennett et al. recites either an "apparatus for monitoring cardiac signals" or a "method for monitoring cardiac signals." Even the final claim (number 29, set forth in Jepson claim format), only recites the patented combination in the context of "detecting capture" of a heart. Since claims 1-5 all include the element recited immediately above, Applicants respectfully assert that this ground of rejection cannot stand. Accordingly, Applicants request the Examiner to withdraw the ground of rejection based on Bennett et al.

Claims 1-5 also stand rejected under 35 USC § 102(e) as being anticipated by Duffin (US 6,230,059). Applicants respectfully assert that the present ground of rejection stands traversed if only a single element found in a rejected claim is not found in the single reference cited against said claim. Thus, while additional distinguishing features may be found to exist between the claimed invention and Duffin, Applicants only need point out a single distinguishing feature to traverse the rejection.

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Applicants respectfully assert that Duffin, like Bennett et al., does not disclose or deal with the issue(s) and elements addressed by the presently pending claims. That is, Duffin also deals exclusively with collection (and filtering) of EGM signals and does not disclose the claimed subject matter regarding synchronized pacing of a ventricle based on sensed P-waves (i.e., atrial depolarizations). As a result, the rejection based wholly on Duffin can be shown to be defective and cannot stand. Accordingly, Applicants respectfully request the Examiner to withdraw this ground of rejection.

Claims 12-14 stand rejected under 35 USC § 102(a) as being anticipated by Nigam et al. (WO 00/61225). Applicants reviewed the Nigam et al. reference and initially noted that the techniques therein appear not to relate to or require any subcutaneous electrodes and, therefore there is no linkage between any such array and synchronized ventricular pacing. Herewith Applicants tender an amendment to independent claim 12 that adds a limitation clearly distinguishing the claim (and claims 13 and 14) from Nigam et al. Namely, Applicants added the following claim limitation: "when a P-wave threshold crossing is sensed by at least a pair of electrodes of a subcutaneous electrode array." Applicants respectfully assert that Nigam et al. does not include this claim limitation and therefore the anticipation rejection based on Nigam et al. fails. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection based on Nigam et al.

#### **IV. Claim Rejections Under 35 U.S.C. §103(a)**

Claims 6-11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bennett et al. (US 5,331,966) in view of Rapach et al. (US 4,907,593) or Pless et al. (US 5,489,293).

Applicants incorporate all the prior remarks regarding Bennett et al. as if fully set forth herein. In addition, Applicants have studied the Rapach et al. and Pless et al. references and respectfully assert that the Examiner has failed to

lodge a *prima facie* obviousness rejection and therefore this ground of rejection should be withdrawn.

Most notably, it appears that Bennett et al. offers no motivation or suggestion to combine the teaching thereof with either the Rapach et al. alleged relatively lower-defibrillation energy technology or the alleged myopotential-mediated rate responsive pacing techniques of Pless et al.

For example, Rapach et al. does not appear to relate to or deal with the subject matter of the present invention as implied at least in part by the following excerpt from the Summary section of Rapach et al.:

It is thus an object of the present invention to provide a method and apparatus for delivering a defibrillation shock sequence which requires lower voltage than conventional defibrillation waveforms.

It is another object of the invention to provide a method of defibrillation which delivers lower energy shocks to the heart than conventional techniques.

Likewise, Pless et al. offers nothing to advance the disclosure of the Bennett et al. reference since Pless et al. appears to relate solely to a rate-responsive pacemaker that utilizes myopotential (i.e., electrical charge due to muscle contractions) to alter the pacing rate of an ambulatory patient. Nothing in the Pless et al. reference appears to relate to or deal with the subject matter addressed by either the Bennett et al. or Rapach et al. references. Accordingly, Applicants respectfully request that the Examiner withdraw this ground of rejection.

#### **V. Conclusion**

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited so that invention claimed therein may pass to timely issuance as U.S. Letters Patent.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein; and no amendment made herein

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was for the purpose of narrowing the scope of any claim unless Applicants have argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

Panken, et al.

By their attorneys,

Date: 12 May '03

  
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